OPERATIONAL RESEARCH POLICY

MSF OCG, April 2019

1. Introduction

As a frontline medical humanitarian organisation providing direct patient care in response to the consequences of epidemics, natural disasters and man-made crises, MSF often has a unique opportunity to pilot and document new intervention and control strategies. Therefore, it is MSF's duty to rigorously document innovative work to be able to share it with others and influence change in policy and practices.

The *MSF OCG Operational Research Policy* is derived from MSF's drive to improve the health outcomes and wellbeing of the patients and populations we serve. MSF is not a research institution; however, its unique position as a primary user of research outcomes as well as a research implementer and funder entails ensuring that the most relevant questions are asked and answered in the best possible way, with rational use of resources.

The *MSF OCG Operational Research Policy* provides the framework to conduct operational research in MSF OCG, while ensuring the safety, privacy and wellbeing of patients under MSF OCG care. This policy, as well as all related documents[1], applies to all MSF OCG's programmes, staff and external partners.

2. Objectives and principles

2.1 Objective of operational research in MSF OCG

Operational research (OR) in MSF OCG aims to improve patient and programme outcomes by evaluating and documenting new, innovative and different intervention strategies, models of care, treatments, preventive measures (vaccines and others), diagnostics etc. Depending on the context of the study, the results might be used to push or influence a policy change, at the country, MSF or international level. If evidence already exists from other contexts, then intervention can be

[1] Data protection policy, data sharing policy, ethical review policy and dedicated SOPs

implemented and documented in a different way; and if there is a true knowledge gap, MSF OCG can address it through formal study.

In MSF OCG, we use the term "operational research" for any type of research, regardless of methodology, as long as the findings are expected to have practical implications and the focus is on the patients and communities that MSF OCG serves. Therefore, the surveyed population should benefit from the findings of OR. OR includes descriptive, observational and experimental studies, including randomised controlled trials.

MSF OCG can decide to invest in research that is not directly linked to the operations or in earlier stages of investigation and development (for example, trying to answer theoretical background questions that will provide evidence for further OR, or participating in clinical trials not directly addressing our beneficiaries (recent example of ROSE clinical trial evaluating safety and efficacy of new rotavirus vaccine). This is a strategic and political choice, and it should be based on a vision and clear plan for what we would like to achieve as the final goal (including advocacy and policy change).

Conceptually, we organise OR around three pillars:

Field epidemiology, with the aim of directly guiding or evaluating operations. Common types include retrospective mortality, nutritional and vaccination coverage surveys, baseline population health assessments, and outbreak investigations.

Retrospective analysis of routinely collected data. In-depth analysis of data collected routinely for patient and project monitoring purposes, with the objective of answering specific questions (beyond routine programme monitoring and evaluation). Separate SOPs are available to guide the process.

Studies. Research designed to answer specific questions with the aim of generating a higher level of generalisable operational or medical knowledge: descriptive, observational (e.g. cross sectional, case-control, cohort) or experimental (randomised controlled trials) studies; using quantitative and/or qualitative[2] methods. This usually requires data to be collected specifically for the purpose of the study.

2.2 Key principles for conducting OR in MSF OCG

1) OR agenda or projects are *aligned with the MSF OCG Strategic Plan and Medico-operational policy*. At the same time, the OR agenda is flexible and allows response to unforeseen situations and arising opportunities.

[2] Qualitative studies follow the same process and criteria as quantitative studies, and the objective of the studies should be directly linked with the operational strategy. Qualitative methods might be used outside of study purposes (assessments, evaluations, guiding health promotion strategies, advocacy, reflection). The objective of those uses should be clearly discussed (see ethics), and whether the results will be used for operational purposes only or if there is intention to use the data beyond the project and patients involved should be defined

2) *The study question is relevant in view of the current evidence*; the aim is that the results of OR will influence operational or clinical decision making or will help in advocacy strategy in documenting exceptional situations, alternative strategies etc.
3) The OR can only be conducted in MSF field, or there is an added value of doing so – "others can't do it" because we have better/unique access to particular populations or situations or capacity to do it in the particular context.

3. OR Procedures

Regardless of the type of the research (see above), the process always follows the same steps:

1) Definition of the research question and study objective, based on a review of the existing evidence: this should include a literature review and an overview of the ongoing studies that might be looking into the same question (e.g. other MSF sections, review of clinical trial registries)**.**

2) Elaboration of a concept note[3], which compiles the study objective(s), justification of the study, methods, resources needed and a dissemination plan. It should include the expected impact (e.g. adaptation of operational strategy, policy change) together with a plan for how this can be achieved. Anyone in the field or HQ can propose a concept note.

3) Validation of the concept note by field (field, coordination) and HQ (cell, OR and technical advisor). These steps should include discussion on the need for formal ethics review, the need for a study advisory group, and the allocation of the resources needed to carry on the research (financial, human and other resources). The principal investigator (PI) should be defined, including possible partnerships. This step is the validation / agreement to proceed with the study. The final decision is taken by the budget holder (cell for OR with dedicated field projects, and department directors for specific OR without assigned projects)

4) Development of the study protocol by the PI and co-investigators.

5) Validation of the study protocol by field and HQ as above, and country authorisation (MOH).

6) Ethics approval if needed (by MSF Ethics Review Board (ERB) and national ERB).

7) Study implementation (data collection, data analysis and report writing).

8) Dissemination of study results through formal report to the MOH, MSF and participants, as well as externally (peer-reviewed papers, scientific conferences, policy-making meetings, etc). This is the responsibility of the PI.

9) Impact evaluation. This should be a continuous process from the study finalisation until dissemination and uptake of the results and eventual policy change (see REMIT below). This is

[3] Concept note: this equals "project proposal" step in project cycle

the responsibility of the PI, or if the PI is no longer engaged with MSF, his supervisor or technical advisor.

3.1 Roles and responsibilities

As OR is an integral part of MSF OCG projects, the decision-making process is co-owned by the field, operational cells and technical advisors (see above).

MSF OCG most often acts as a sponsor for OR conducted in its projects and has overall responsibility to ensure that the OR is conducted according to the protocol. The director of the department in charge of the research is the overall responsible (with this responsibility delegated to assigned person). The lead institution (MSF, Epicentre or external partner) is responsible for identifying a competent PI (and ensuring the continuity of the study in case the PI leaves the project/study) (see "Research staff and partnerships" below) who then takes the responsibility for implementing the OR and disseminating the results.

The role of OR coordinator is to assure the research agenda is in line with strategic plan and medico-operational policy; that the OR activities are aligned between different departments in MSF OCG and among OCs and to assure the procedures are respected, including ethics oversight.

3.2 REMIT (REsearch Management and Impact Tool)

MSF OCG supports the intersectional initiative on monitoring research and its impact through the REMIT platform. All studies will be followed through REMIT, from the concept until final dissemination and impact analysis.

4. Research staff and partnerships

Human resources needed for implementation of OR should be defined at the validation phase (concept note/protocol).

Principal investigator The PI will be assigned at the stage of validation (could be MSF staff or Epicentre/external partner) and will take full responsibility for writing the protocol and implementing the OR. Depending on the type of OR, sometimes this could be field or HQ staff (for example, for field epidemiology or retrospective data analysis), but in most cases a dedicated PI with appropriate expertise and experience will be needed for full-time follow-up.

Ministry of health

Any OR should involve counterparts at local and national level, and the appropriate MOH counterparts should be engaged from the study design phase. If this is not possible, this needs to be justified and discussed.

Other policy makers

Involving policy makers at the national and international level from the study design stage can facilitate integration of research findings into policy change.

Research partnerships

For MSF OCG, Epicentre is the main and preferred research partner – based on the long history of collaboration, knowledge of MSF fields and flexibility.

For studies that need expertise beyond MSF/Epicentre, OCG can engage in research partnerships (this can be international or national academic institutions, or other government or non-government organisations). The partnership should be chosen according to the relevant expertise and experience in the topic. The added value of engaging in a particular partnership needs to be justified, and the final validation is done by the medical director (including for partnerships with national research institutions) for any research involving human subjects. For others, department directors are responsible for a given partnership. No commitments should be made before this and formal signature of MOU and/or data/material sharing agreement.

Masters and PhD students

When feasible and pertinent, MSF OCG can facilitate access to medical or operational data for master thesis for MSF staff (and exceptionally for others) if the proposed topic is of direct interest to MSF. Ideally, the master thesis should be based on retrospective analysis of routine data or on a literature review of interest; prospective data collection in the field is discouraged (unless exceptionally relevant)[4]. MSF OCG might also exceptionally facilitate PhD theses for long-term staff working on topics of direct interest to MSF OCG or, exceptionally, on topics for which we lack expertise. The same OR process needs to be followed and a data sharing agreement signed before the sharing of data.

5. Data sharing and protection

5.1 Data sharing

MSF OCG commits to share health data collected in its programmes and within OR. Refer to MSF data sharing policy for more details.

5.2 Data protection

MSF OCG commits to protect data it collects. Refer to MSF data protection policy for more details.

6. Ethics

All studies conducted by MSF OCG that involve human participants or human samples should be subject to prior approval by MSF and national ERB. All types of studies (descriptive or analytical, quantitative or qualitative) are subject to the same process. The overall responsibility lies with medical director, with the task delegated to OR coordinator.Retrospective analysis of routinely collected data does not require MSF ERB review provided it fulfils the exemption criteria.

[4] Validation (ERB process) and implementation of field studies is a time and resource consuming process, which is not aligned with timelines of masters thesis

Retrospective mortality, vaccination coverage, nutrition and KAP[5] surveys who follow standard template also do not require ERB review. The exemption is provided by the OR coordinator on the basis of the protocol (or concept note for retrospective analyses) and exemption template. This exemption is only applying to MSF ERB review; the need for national ERB needs to be verified at the country level with appropriate medical authorities.

Surveys or evaluations conducted purely for project planning or evaluation purposes, without any intention of external communication, might not need ERB approval (but still need appropriate authorisations). The need for ERB approval for any quantitative or qualitative study should be defined during validation of the concept note.

7. Dissemination of results

Any study conducted should have a final report written and validated by the field and HQ, and results should to be shared with local and national authorities, as appropriate. Interim reports might be important for studies that include longer-term data collection.

All prospective studies should also aim to have results published in peer-reviewed journals (or provide justification why this cannot or should not be done) and, if relevant, be shared at scientific conferences. In both cases, authors need to seek validation for the submission from the cell, OR coordinator, national partners (if pertinent) and appropriate technical/medical advisor in MSF OCG before submitting abstracts or manuscripts.

MSF has an open-access policy for publishing – all manuscripts should be submitted to journals that allow for open access (or justify exemption if this is not possible). In addition, MSF makes all its scientific research and commentary articles published in peer-reviewed journals available to the public free of charge on its website, *MSF Field Research*.

For key studies, MSF also commits to publish study protocols (or make them available through *MSF Field Research*).

[5] As of April 2019, retrospective mortality, vaccination coverage and nutritional survey templates have been validated by MSF ERB. KAP surveys are pending